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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,107	10/30/2001	Grant L. Schoenhard	13726US01	8970

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EXAMINER
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HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/05/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/000,107

Applicant(s)

SCHOENHARD, GRANT L.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10/30/2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-8 are drawn to a method of increasing the potency of an anti-microbial agent comprising an ABC transporter and an opioid inhibitor sufficient to reduce efflux of the anti-microbial agent, classified in class 435, subclass 32.
  - II. Claims 9-16 are drawn to a method of increasing the potency of an anti-microbial agent comprising an ABC transporter and an opioid inhibitor sufficient to increase the intracellular concentration of the anti-microbial agent, classified in class 435, subclass 252.4.
  - III. Claims 17-24 are drawn to a composition for treating microbial infection comprising a substrate of an ABC drug transporter, classified in class 435, subclass 235.1.
  - IV. Claims 25-32 are drawn to a method of enhancing the anti-microbial agent against a microbe, classified in class 435, subclass 71.2.
  - V. Claims 33-40 are drawn to a method of suppressing growth of a microbe expressing an ABC drug transporter protein, classified in class 435, subclass 71.3.
  - VI. Claims 41-44 are drawn to a method of inhibiting a microbial P-glycoprotein homologue in a patient suffering from a microbial infection by

administering an inhibitor selected from the group consisting of naltrexone, naloxone, and nalmefene, classified in class 435, subclass 244.

- VII. Claims 45-47 are drawn to a method of inhibiting a microbial P-glycoprotein homologue in a patient suffering from a microbial infection by administering an inhibitor having the recited formula, classified in class 435, subclass 252.1.
- VIII. Claims 48-55 are drawn to a composition for the treatment of a microbial infection comprising a inhibitor capable of inhibiting a drug transporter protein, classified in class 435, subclass 243.
- IX. Claims 56-57 are drawn to a method of identifying a compound for improved treatment of microbial infections, classified in class 435, subclass 29.
- X. Claim 58 is drawn to a method of screening for an opioid inhibitor of an ABC drug transporter comprising a determination step, classified in class 435, subclass 239.
- XI. Claims 59-60 are drawn to a method of screening for an opioid inhibitor of an ABC drug transporter comprising a contact step, a measuring step, a comparison step and identification step, classified in class 435, subclass 170.
- XII. Claims 61-62 are drawn to a method of treating a microbial infection in an animal comprising administering an ABC drug transporter inhibitor and an anti-microbial agent, classified in class 435, subclass 340.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and any of II, IV-VII or IX-XII are related as methods. The methods are distinct as claimed because they have different methods with different method steps; different functions and the effects have different final outcomes. Group I is drawn to a method of increasing the potency of an anti-microbial agent comprising an ABC transporter and an opioid inhibitor sufficient to reduce efflux of the anti-microbial agent. This method is unlike any other method. For instance, the method of Group II has different steps and uses different reagents, wherein group II is sufficient to increase the intracellular concentration of the anti-microbial agent, which is entirely different than reducing efflux of the anti-microbial agent. The method of group I does not produce the same results as any of groups II, IV-VII or IX-XII. The other groups are drawn to enhancing methods, suppressing methods, inhibiting methods, identification methods, screening methods wherein each group produces different effects and different functions when compared to the other groups. Therefore, the inventions are unrelated.

Inventions III and VIII are related as different products. The products are distinct as claimed because they have different structures and different uses. Group VIII is drawn to a composition comprising an inhibitor capable of inhibiting a drug transporter protein while group III is drawn to a composition comprising different products. Each product comprises agents that have different functions, effects and are capable of use without the other. For instance, the composition of Group III comprises a substrate of an ABC drug transporter while the composition product of group VIII does not. Therefore,

the products of the inventions are distinct as claimed because each composition has a different structure, comprises different agents and produces different effects when compared to the other group.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for any of Groups II-XII, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines   
September 3, 2003

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600